FLORA.1100

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s):	Kleiman *et al.*	Atty Docket No.:	FLORA.1100
Serial No.:	09/899,432	Group Art Unit:	1617
Filed:	07/06/2001	Examiner:	Shobha Kantamneni

TITLE: **ANTIVIRAL COMPOSITION AND TREATMENT METHOD**

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class mail in an envelope addressed to " Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" on:

Date: _____ By: _____

Printed Name: _____

AFFIDAVIT
PURSUANT TO 37 C.F.R. §1.132

Assistant Commissioner of Patents
Alexandria, VA 22313-1450

Dear Assistant Commissioner:

STATE OF ARIZONA)
:
COUNTY OF MARICOPA)

I, David Ashley, being duly sworn, depose and say as follows:

I received a Bachelors of Science in Chemistry from Arizona State University in May of 1987. I have been employed by International Flora Technologies, Inc., (Technical Department) since 2003 where I serve as a chemist. Previously, I was employed at Safety-Kleen Systems, Inc., where I served as Compliance Manager from 2002-2003. I have also worked in various technical and managerial capacities at Onyx Environmental Services (Salesco Systems USA, Inc.), ADFlex Solutions Inc., and Revlon Consumer Products Corporation. I have over fourteen years of experience in analytical chemistry, environmental, health, and safety management. I am a Certified Hazardous Material Manager, and a member of the American Chemical Society.

I have undertaken an extensive review of United States Patent Application Serial No. 09/899,432. The invention referenced therein is directed to methods for treating virus-induced and inflammatory diseases utilizing compositions that include monounsaturated long chain alcohols in combination with long chain fatty acid salts and fatty acid esters. This combination accounts for a dramatic increase in antiviral activity including against the Herpes Simplex Virus (HSV-1) strain (6143), as discussed on pages 26-27 of the application as filed.

Exhibit 1 displays the results of a standard plaque reduction assay to determine the antiviral activity of n-docosanol (A) and K100 (B). K100 is refers to the combination of monounsaturated long chain alcohols, jojoba-derived fatty acid salts, and fatty acid esters (specifically, jojoba esters), and is taught in Application Serial No. 09/899,432.

Screening for antiviral material was performed through a standard plaque reduction assay. A plaque represents a clearing of cells in the culture monolayer due to the viral infection and subsequent death of the cells. Vero cells (epithelial-like cells originally derived from the kidney of the normal African green monkey) were cultured in Eagles Minimal Essentials Medium supplemented with 10% heat inactivated Fetal Bovine Serum, 100 units/ml penicillin, 2.5 μg/ml Amphotericin B, and 10 μg/ml Gentamicin, at 36-38°C in a humidified chamber atmosphere of 5-7% CO_2. 24 hours prior to infection, noncytotoxic concentrations of either n-docosanol, or K100 were added to the cultures. Some cultures were not treated with either n-docosanol or K100 so as to include controls. The virus VML-6143 strain of Type-1 Herpes Simplex virus (HSV-1), sensitive to all known anti-HSV drugs, was used to infect Vero cells. 48 hours after infection with HSV-1 (6143 strain), cultures were washed, fixed and stained. Plaques were counted, and data is presented as averages of duplicate cultures in Tables A (n-docosanol) and B (combination of monounsaturated long chain alcohols, long chain fatty acid salts and fatty acid esters) of Exhibit 1. A logarithmic regression to find the 50% kill concentration was performed on the results of the combination of the present invention and on the results of n-docosanol alone. When comparing the kill concentrations of the combination of the present invention and n-docosanol alone, it is shown

that the combination of the present invention is approximately 100 times more effective than n-docosanol alone in killing the HSV-1 Strain 6143.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true. I further declare that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful and false statements may jeopardize the validity of the subject patent application or any patent issued thereon.

I further declare that I have received no special compensation or consideration for making this affidavit, nor have I been in any way told, either directly or by implication or inference, by anyone that my employment by International Flora Technologies, Inc., or my professional advancement or other matters of personal or professional interest to me depend in any way on whether or not I make this affidavit or the content thereof. I further declare that I make this affidavit of my own free will and choice without any duress or influence of any kind, believing fully in the truth of the statements made by myself herein.

David Ashley

I, Carol Hynes, a Notary Public in and for the County and State aforesaid, do hereby certify that David Ashley, whose name is subscribed to the foregoing instrument, appeared before me this day in person and acknowledge that he signed, sealed and delivered the said instrument as his free and voluntary act and deed for the uses and purposes therein set forth.

Given under my hand and Notary Seal this 7th day of Nov 2007.

My commission expires on Nov 29, 2007

SEAL

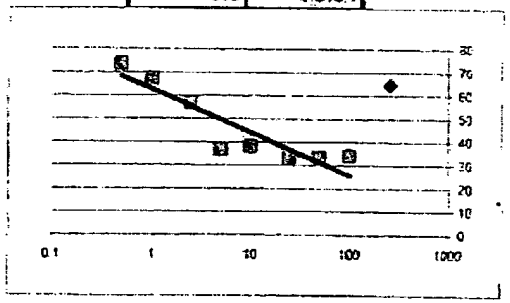
OFFICIAL SEAL
CAROL HYNES
NOTARY PUBLIC - State of Arizona
MARICOPA COUNTY
My Comm. Expires Nov. 29, 2007

EXHIBIT 1

A

n-Docosanol

Conc (mg/mL)	% Compared to Untreated Colonies
250	64.58
100	34.03
50	33.33
25	33.33
10	38.19
5	36.81
2.5	56.94
1	67.36
0.5	73.61



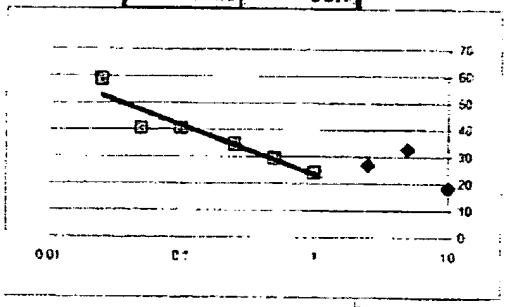
y = -8.06856643947301Ln(x) + 62.7072648371868

x= **4.830257**
y= 50.00008

B

K-100

Conc (mg/mL)	% Compared to Untreated Colonies
10	18.3
5	32.7
2.5	26.8
1	24.2
0.5	29.4
0.25	34.6
0.1	40.5
0.05	40.5
0.025	58.7



y = -8.01198033621572Ln(x) + 23.2057185088178

x= **0.035286**
y= 50.00003

result **136.8904305**
100 times more effective

EXHIBIT 1